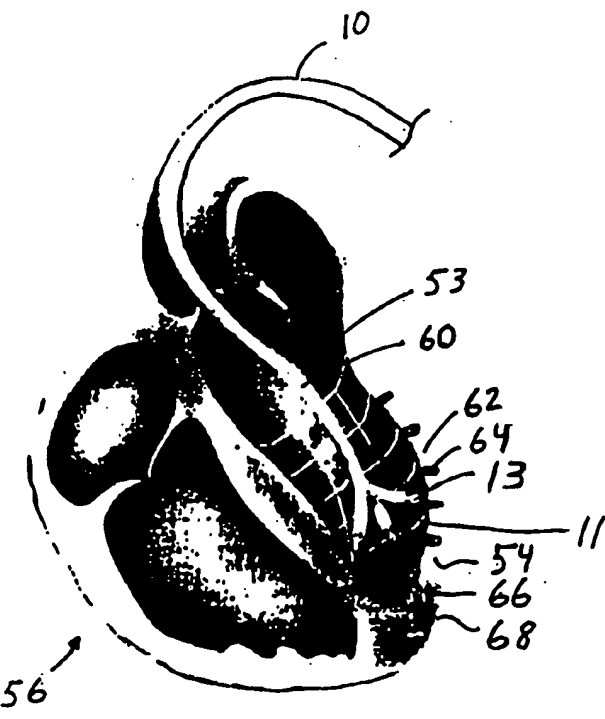


PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/39	A1	(11) International Publication Number: WO 99/17671 (43) International Publication Date: 15 April 1999 (15.04.99)
(21) International Application Number: PCT/US98/20799 (22) International Filing Date: 2 October 1998 (02.10.98) (30) Priority Data: 08/942,874 2 October 1997 (02.10.97) US 08/947,290 7 October 1997 (07.10.97) US 09/107,077 29 June 1998 (29.06.98) US (71) Applicant: CARDIOGENESIS CORPORATION [US/US]; 540 Oakmead Parkway, Sunnyvale, CA 94086 (US). (72) Inventors: AITA, Michael; 4067 North Farwell Avenue, Shorewood, WI 53211 (US). SIMPSON, Carl, J.; 1335 Country Way, Los Altos, CA 94022 (US). KESTEN, Randy, J.; 181 Ada Avenue #41, Mountain View, CA 94043 (US). (74) Agents: LYNCH, Edward, J.; Heller, Ehrman, White & McAuliffe, 525 University Avenue, Palo Alto, CA 94301-1900 (US) et al.		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NI, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: TRANSMYOCARDIAL REVASCULARIZATION USING RADIOFREQUENCY ENERGY		
(57) Abstract <p>The invention is directed to a system and method for revascularization of a patient's heart tissue by at least one burst of RF energy over an interval of about 1 to about 500 msec, preferably about 30 to about 130 msec. The device preferably has an elongated insulated, electrical conducting shaft with an uninsulated distal tip which is configured to emit RF energy. A method is described for myocardial revascularization of a human heart in which an elongated flexible device is used which includes a radiofrequency ablation device. In some embodiments, the device is configured to be introduced percutaneously, on other embodiments, the device is configured to be introduced intraoperatively. The RF energy emitter is advanced to a position adjacent a desired area of the heart wall. The device is activated, moving tissue to form a revascularization channel.</p> 		

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

TRANSMYOCARDIAL REVASCULARIZATION USING RADIOFREQUENCY ENERGY

RELATED APPLICATIONS

5 This application is a continuation-in-part of copending application Serial No. 08/942,874, filed October 2, 1997, and application Serial No. 08/968,184, filed November 12, 1997, which are both continuations of application Serial No. 08/517,499, filed August 9, 1995. All of the above-referenced applications are hereby incorporated by reference in their entirety.

10 BACKGROUND OF THE INVENTION

This invention is directed to the ablation or disruption of tissue in the wall of a patient's heart and particularly to form channels within the heart wall in order to perform transmyocardial revascularization (TMR), to deliver therapeutic or diagnostic agents to various locations in the patient's heart wall or for a variety of other utilities.

As presently used, TMR involves forming a plurality of channels in a ventricular wall of a patient's heart by means of laser energy. The first clinical trials of the TMR procedure using laser energy were performed by Mirhoseini et al. See for example the discussions in Lasers in General Surgery (Williams & Wilkins; 20 1989), pp. 216-223. Other early disclosures of the TMR procedure are found in an article by Okada et al. in Kobe J. Med. Sci 32, 151-161, October 1986 and in U.S. Patent 4,658,817 (Hardy). These early references describe intraoperative TMR procedures which require an opening in the chest wall and include formation of channels completely through the heart wall starting from the epicardium.

U.S. Patent NO. 5,554,152 which issued on December 20, 1994 (Aita et al.), which is incorporated herein in its entirety, describes a system for TMR which is introduced through the chest wall either as an intraoperative procedure where the chest is opened up or as a minimally invasive procedure where the system is introduced into the patient's chest cavity through small openings in the chest by means of a thoroscope.

In U.S. Patent No. 5,389,096 (Aita et al.) a percutaneous TMR procedure is described wherein an elongated flexible laser based optical fiber device is introduced through the patient's peripheral arterial system, e.g., the femoral artery, and advanced through the aorta until the distal end of the device extends into the patient's left ventricle. Within the left ventricle, the distal end of the optical fiber device is directed toward a desired location on the patient's endocardium and urged against the endocardial surface while a laser beam is emitted from its distal end to form the channel.

Copending application Serial No. 08/078,443, filed on June 15, 1993 (Aita et al.), which is incorporated herein in its entirety, describes an intravascular system for myocardial revascularization which is percutaneously introduced and advanced into the left ventricle of the patient's heart where laser energy initiates revascularization through the endocardium and into the myocardium. This procedure eliminates the need of the prior procedures to open the chest cavity and to penetrate the epicardium in order to form the channel through the endocardium into the myocardium.

The laser based revascularization procedure has been shown to be clinically beneficial to a variety of patients, particularly patients who were, for the most part,

not suitable candidates for by-pass surgery or for minimally invasive procedures such as angioplasty or atherectomy. However, to date the equipment for laser based systems has been quite expensive. What has been needed is a system which is less expensive than but as clinically effective as laser based systems. The
5 present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

The present invention is directed to a method and system for the revascularization of a region of a patient's heart by ablating or disrupting tissue in said region with emissions of radiofrequency (RF) energy and is particularly
10 directed to the methods and systems to ablate or disrupt tissue in the patient's heart wall to form channels therein by means of such RF energy.

One method includes the step of inserting an elongated shaft having an RF energy emitter into a patient's vasculature. Preferably, a system for guiding the device is also provided. The RF energy emitter is guided to the interior of the left
15 ventricle and positioned against a desired portion of the ventricle's inner wall. Then, the RF energy emitter is activated to remove or otherwise injure tissue. The RF energy emitter may be advanced so as to remove tissue until a channel or disrupted area is formed to the desired depth. Methods for controlling the depth of channel formation include fluoroscopic or ultrasonic visualization or advancing the
20 revascularization means a fixed distance. In addition, penetration limitation can be achieved with mechanical penetration limiters such as those taught in copending U.S. Application Ser. No. 08/486,978, which is hereby incorporated by reference in its entirety. The RF energy emitter is repositioned against another portion of the

heart wall and the process is repeated until enough channels or regions of ablated tissue are formed to provide the desired revascularization.

In accordance with one embodiment of the invention, tissue is ablated within a patient's heart wall by means of one or more bursts of RF emissions over
5 intervals of about one to about 500 msec and preferably about 30 to about 130 msec. A radiofrequency burst may comprise a continuous emission or discontinuous emission, i.e. be pulsatile, and, if pulsatile, may involve a plurality or train of pulses which may or may not be of the same width (duration), frequency or amplitude.

10 The RF emissions are preferably controlled so that heart tissue is exposed to the RF energy over a desired period and particularly over a period which will avoid interfering with the patient's heart beat, e.g., just after the R wave but before the T wave. One to about 10 bursts of RF energy may be required to effectively form the desired channel within the patient's heart wall and preferably one burst of RF
15 emission is delivered per heart cycle. The RF energy source generally should have a peak power output of about 150 to about 500 watts, preferably about 200 to about 300 watts.

It also may be desirable to operate the RF energy emitter at more than one energy level. Initially, the channel formation or tissue disruption may be performed
20 at a relatively high energy level to position and anchor the RF ablation device. For greater control, the remainder of the procedure may be performed at a lower energy level.

One presently preferred system for revascularizing a patient's heart wall includes an RF energy transmitting member which has a proximal end, and an

uninsulated distal tip configured to emit RF energy. The system is introduced into the patient and advanced within the patient until the uninsulated distal tip thereof is disposed adjacent to a surface of the patient's heart wall. At least one burst of RF energy from an RF energy source is transmitted through the RF energy transmitting member to the uninsulated distal tip thereof. The RF energy is then emitted from the distal tip and into the heart wall in contact with said distal tip. In preferred embodiments, the channel formed in the heart wall preferably has an aspect ratio, i.e., depth to width, of at least 1, preferably at least 2.

Any particles of tissue produced by the RF energy emitter have the potential to create emboli if allowed to escape into the patient's circulatory system. Accordingly, in a number of these embodiments, the RF energy emitter includes lumens for perfusion and aspiration to remove the particles from the patient's body. Alternatively, the RF energy emitter is configured to produce particles small enough to safely propagate through the smallest branches of the patient's vasculature, approximately 6-10 μm in diameter.

One embodiment of the invention utilizes a percutaneous approach in which a flexible RF energy emitter is advanced through the patient's vasculature until a distal portion of the system enters a heart chamber such as the left ventricle. The RF energy transmitting member is advanced so that the uninsulated distal tip which emits RF energy contacts the interior surface of the heart wall which defines in part the heart chamber. At least one burst of RF energy is emitted from the uninsulated distal tip of the system into the patient's heart wall wherein tissue is ablated or otherwise disrupted, resulting in the revascularization of the heart wall region.

Another embodiment of the invention involves a minimally invasive approach

where a small incision is made in the patient's chest and with or without the benefit of a trocar sheath, an elongated RF energy transmitting member is advanced into the patient's chest cavity until the uninsulated distal tip of the RF transmitting member contacts the exterior of the patient's heart. One or more bursts of RF energy are emitted from the uninsulated distal tip so as to ablate or disrupt tissue within the patient's heart wall causing the revascularization thereof, as in the previously discussed embodiments of the invention. A similar procedure may be used in conjunction with an open chest procedure such as coronary by-pass surgery or in other surgical procedures, as is the case with laser based transmyocardial revascularization.

The RF energy emitter preferably includes an RF energy transmitting member which is insulated along its length except for the distal tip thereof which is uninsulated and which is configured to contact the surface of the heart wall and to emit bursts of RF energy therefrom into adjacent tissue of the heart wall. The uninsulated distal tip can have a diameter of about 0.025 to about 0.2 inch (0.64-5.1 mm), preferably about 0.04 to about 0.08 inch (1-2 mm) and a length of about 0.1 to about 5 mm, preferably about 1.5 to about 3.5 mm. The distal tip may be solid or hollow and may be relatively sharp or blunt. However, it should not be sharp enough to penetrate the tissue of the heart wall when pressed against the wall to maintain contact during the emission of RF energy bursts. The average power level should be about 50 to about 500 watts, preferably about 100 to about 300 watts. The frequency of the RF current should not be less than 100 kHz and preferably is about 250 to about 500 kHz.

The method and system of the invention effectively ablates or disturbs tissue

within the patient's heart wall to revascularize the ablated region and particularly can be used to form channels within the heart wall. These and other advantages of the invention will become more apparent from the following detailed description of the invention and the accompanying exemplary drawings.

5

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic illustration of a system for revascularizing heart tissue which embodies features of the invention.

FIG. 2 is a transverse cross-section of the RF energy transmitting member of the system shown in FIG. 1 taken along the lines 2-2.

10

FIG. 3 is a schematic illustration of the one shot shown in FIG. 1.

FIG. 4 is a schematic illustration of a system for generating trigger signals based upon the patient's heart beat.

15

FIG. 5 is an elevational view of a delivery system for the RF energy emitter for positioning the operative distal end thereof adjacent to the endocardium of a patient's heart wall.

FIG. 6 is a schematic elevational view, partially in cross-section, of a human heart showing revascularization of the myocardium according to the invention.

FIG. 7 is a schematic longitudinal cross-sectional view of the distal portion of a deflectable elongated RF system which embodies features of the invention.

20

FIGS. 8 and 9 are schematic longitudinal cross-sectional views of RF systems useful in the practice of this invention.

DETAILED DESCRIPTION OF THE DRAWINGS

FIGS. 1 and 2 depict an RF system 10 embodying features of the invention which includes an RF energy transmitting member 11 having a proximal end configured for electrical connection to a source 12 of RF energy and an uninsulated
5 exposed distal end 13 which is configured to emit pulsed RF energy received from the source and transmitted through the RF energy transmitting member. The RF energy transmitting member 11 includes an electrical conductor 14 which may be hollow or solid, a single or multiple strand and an insulating jacket 15 formed of suitable insulating polymeric material. A suitable source of RF energy is the
10 Excaliber RF Generator from Aspen Laboratories (ConMed, Englewood, CO, USA).

The output from the RF energy source 12 is pulsed by pulse-trigger system 16 which includes a one-shot 17, such as CD4047 sold by National Semiconductor, configured to receive trigger signals 18 through electrical conductor 19 and generate in response a pulsed output signal 20 connected to a NPN transistor 21.
15 The pulsed output signal 20 from the one-shot 17 actuates the transistor 21 for the duration of the output signal. The output of the transistor 21 is connected to reed relay 22 which is configured to close upon receiving the output from the transistor 21. The output of the reed relay 22 is connected in series to the foot switch 23. When the foot switch 23 is closed and reed relay 22 is closed, the RF energy
20 source is actuated to emit RF energy for the duration of the output of the reed relay 22.

FIG. 3 illustrates in more detail the one-shot shown in FIG. 1 which has 14 pins, identified as pins a-n in FIG. 3. The one-shot shown in FIG. 3 has the pins designated with letters a-n to avoid confusion with other reference numbers used

herein. The one-shot model number CD4047 has these pins numbered 1-14. The trigger signal 18 from an ECG unit is received by pin h and upon receipt of the trigger signal an on signal is emitted from pin j. The duration of the on signal from pin j is controlled by the resistance R and capacitance C from the RC circuit
5 connected to pins a-c as shown. The resistance R can typically range from about 0.1 to about 1 meg ohm and the capacitance can typically range from about 0.08 to about 0.12 microfarads to control the duration of the pulses of output signal 20 from about 50 to about 300 msec.

FIG. 4 schematically illustrates a system of generating trigger signals 18
10 based upon the patient's heart cycle 30. The signals from the patient's heart 31 are detected with a conventional ECG unit and the detected signals are transmitted to a trigger generating system 32 which may also be contained in the ECG unit. The trigger signal generating system 32 is preprogrammed to emit one or more trigger signals 18 at a predetermined time between the R and the T wave of the heart cycle
15 30.

Reference is made to FIG. 5 which illustrates a system for the percutaneous delivery of an RF system which has an outer catheter 40, a shaped distal end 41, a port 42 in the distal end of the outer catheter and an inner lumen extending within the outer catheter to the port in the distal end. This system also includes an inner
20 catheter 44 which is slidably and rotatably disposed within the inner lumen of the outer catheter 40 and which has a shaped distal section 45, a distal end 46, a port 47 in the distal end of the inner catheter and an inner lumen 48 extending therein to the port in the distal end. An RF energy emitter 50 is slidably disposed within the inner lumen of inner catheter 44. The distal section 45 of the inner catheter 44 is at

an angle with respect to the main shaft section 51 of the inner catheter to orient the RF energy emitter 50 extending out the distal end of the inner catheter. In this manner the disposition of the distal end 52 of the RF energy emitter 50 can be controlled by raising and lowering and rotation of the RF energy emitter within the
5 inner lumen of the inner catheter 44 and the inner catheter within the inner lumen of the outer catheter 40. The distal end 52 of the RF energy emitter 50 is thus pointed in a desired direction to the endocardium defining the left ventricle 53. Longitudinal and rotational movement of the inner catheter 44 provides access to a large region of the endocardium.

10 Referring to FIG. 6, the present invention also comprises a method for revascularizing the myocardium 54 of a human heart 56. An RF system 10 including an elongated shaft 60 with an RF energy emitter 50 disposed at the distal end is inserted into the vasculature of a patient, generally through one of the major vessels by the conventional Seldinger technique. The RF energy emitter 50 is
15 advanced into the left ventricle 53 and positioned against a desired portion of the heart muscle 62 in need of increased blood circulation due to cardiovascular disease. The RF energy emitter 50 is activated and urged against the muscle 62 to effect removal of tissue, forming the revascularization channel 64. The tissue region disturbed or ablated should extend a desired distance through the
20 endocardium 66 and into the myocardium 54 without perforating the epicardium 68. The RF energy emitter 50 is deactivated, withdrawn from channel 64 and repositioned against another portion of muscle 62.

In another method of the invention (not shown) an RF system 10 having an RF energy emitter 50 on the distal end is introduced through a small opening in the

patient's chest wall. RF system 10 is advanced until the RF energy emitter 50 is positioned against the ischemic portion of the heart muscle 62. The RF energy emitter 50 is activated and urged towards the muscle 62. Tissue is removed sequentially from the epicardium 68, the myocardium 54 and the endocardium 66 to form the revascularization channel 64 into the left ventricle 53. As above, the RF energy emitter 50 is then deactivated, withdrawn from the muscle 62 and repositioned. In either method, the operator repeats the process until a sufficient number of channels 64 or similar revascularization sites are formed in muscle 62 to treat the ischemic condition.

10 In operation, the RF energy emitter 50 may be maintained in position on the heart muscle 62 by a controlled advance and gentle pressure, to insure that the RF energy emitter 50 is not dislodged during formation of the channel. Alternatively, the RF energy emitter 50 can be maintained in place by applying a vacuum at the distal tip thereof.

15 In embodiments where the RF energy emitter 50 allows rapid, intermittent switching between active and inactive states, the operation may be synchronized with the patient's heart cycle to avoid channel formation during the vulnerable period of the heart cycle. Preferably, the RF energy emitter 50 is subject to automatic control means which prevents operation during the T-wave portion of the ECG, as known in the art.

20 Additionally, the RF energy emitter 50 may operate at two or more energy levels. Preferably, the initial tissue removal to penetrate the endocardium 66 is performed at a relatively high energy level. The rapid channel formation at this energy level helps anchor the RF energy emitter 50 within the channel 64. The

remainder of the tissue removal may be performed at a lower energy level to provide slower channel formation and greater control.

In the embodiment depicted in FIG. 2, a plurality of control lines 70 are connected at their distal ends to the distal end 72 of shaft 60 such as by adhesive bonding. Adhesive bonding may utilize any of a variety of adhesives, including cyanoacrylate. At least two, and preferably four, control lines 70 are thus axially, and preferably symmetrically, disposed about shaft 60. Axial movement of control lines 70 will thus change the angle of deflection of distal end 72 of shaft 60 with respect to its proximal end. A mechanism (not shown) such as a ring or knob may be attached to the proximal ends of control lines 70 to allow manipulation of control lines 70. Control lines 70 are preferably approximately 3-mil stainless steel wire, but may be similar filaments, such as nylon, or other suitable materials having appropriate tensile strength.

In addition, an outer tubular member 74 preferably encloses control lines 70 and shaft 60, forming a protective covering. Outer tubular member 74 is secured at its distal end to distal end 72 of shaft 60, rearward of RF energy emitter 50. In order to facilitate precise control of the tip during the procedure, control lines 70 are routed through spaced apart channels 76 that are attached to the outer surface of shaft 60. Channels 76 are preferably constructed of 30 gauge polyamide tubing. Control lines 70 are thus guided to remain both separated and within well controlled areas on the exterior of shaft 60, thus allowing for the accurate guidance of the RF system 10 through the remote manipulation of control lines 70.

Another means for guiding shaft 60 and RF energy emitter 50 into a proper position within the heart is to place the shaft 60 within a deflectable guiding catheter

having dual axis steerability, for an added degree of steerability and control. Co-pending application, S.N. 08/438,743 filed May 10, 1995, entitled DELIVERY SYSTEM AND METHOD FOR MYOCARDIAL REVASCULARIZATION discloses such a system and is hereby incorporated in its entirety by reference thereto. In
5 practice, the positioning of the device may be viewed by esophageal ultrasound imaging, trans-thoracic ultrasound imaging and trans-thoracic fluoroscopic imaging. Accordingly, it may be desirable to add one or more radiopaque marker bands to the distal end 72 of shaft 60, for fluoroscopic imaging. RF energy emitter 50 may thereby be aimed and controlled for forming channels 64 in the myocardium 54 of
10 the ischemic heart muscle 62.

Alternative means of ablation are suitable, including thermal and other radiation means. For example, FIG. 8 illustrates the distal portion of an RF system 100 which has a thermal ablator 78. The thermal ablator 78 has an electrode 80 wrapped around thermally-conductive probe 82 and extending the length of the
15 system 100. The diameter of probe 82 should be from about 1.0 to 5.0 mm. The proximal ends of the electrode 80 is are connected to a radiofrequency generating means (not shown). Applying radiofrequency energy at suitable frequency and power through electrode 80 produces resistive heating transmitted through probe 82. Generally, energy from about 30 MHz to about 10 GHz is suitable to generate
20 sufficient heat at probe 82 to ablate heart tissue.

Radiofrequency energy may also provide inductive heating as shown in FIG. 9. The distal portion of an RF system 10 has a ferrite probe 84 on the end. A radiofrequency generating means (not shown) irradiates the patient's body with energy at a frequency to which body tissue is relatively transparent but the ferrite

Radiofrequency energy may also provide inductive heating as shown in FIG. 9. The distal portion of an RF system 10 has a ferrite probe 84 on the end. A radiofrequency generating means (not shown) irradiates the patient's body with energy at a frequency to which body tissue is relatively transparent but the ferrite probe readily absorbs, generating ablating heat.

5

EXAMPLE

Eighteen channels were made in the heart of a live, anesthetized medium size dog by means of pulsed RF energy. The wattage and the size and type of distal tip of the RF delivery system were varied to determine the nature of the

channels formed which result from such variations. The results are set forth in the table below.

WATTAGE	DISTAL TIP TYPE	UNINSULATED LENGTH	PULSE DURATION	# OF PULSES
200 watts	Hollow	0.05 inch	100 msec	6
200 watts	Hollow	0.05 inch	100 msec	5
200 watts	Hollow	0.05 inch	100 msec	5
200 watts	Hollow	0.05 inch	100 msec	6
200 watts	Hollow	0.05 inch	100 msec	5
200 watts	Hollow	0.05 inch	100 msec	5
300 watts	Hollow	0.05 inch	100 msec	3
300 watts	Hollow	0.05 inch	100 msec	4
300 watts	Hollow	0.05 inch	100 msec	4
300 watts	Hollow	0.05 inch	100 msec	5
300 watts	Hollow	0.05 inch	100 msec	4
300 watts	Hollow	0.05 inch	100 msec	5
300 watts	Solid	0.15 inch	100 msec	4
300 watts	Solid	0.15 inch	100 msec	5
300 watts	Solid	0.15 inch	100 msec	6
300 watts	Solid	0.15 inch	100 msec	7
300 watts	Solid	0.15 inch	100 msec	5
300 watts	Solid	0.15 inch	100 msec	5

Those skilled in the art will recognize that various changes can be made to the invention without departing from the scope thereof. There has been described herein various systems and methods for myocardial revascularization employing an elongated revascularization device. The revascularization may be performed from

5 within the left ventricle or from the exterior of the heart. Various modifications to the present invention will become apparent to those skilled in the art from the foregoing description and accompanying drawings. Accordingly, the present invention is to be limited solely by the scope of the following claims.

WHAT IS CLAIMED IS:

1. An RF system for performing TMR, comprising:
 - a) an elongated shaft having a proximal end and a distal end configured to access a patient's heart; and
 - 5 b) an RF energy emitter disposed at the distal end of the elongated shaft configured to emit RF energy to surrounding tissue.
2. The RF system of claim 1 further comprising an elongated RF energy transmitting member having a distal end electrically coupled to the RF energy emitter.
- 10 3. The RF system of claim 1 wherein the RF energy transmitting member further comprises an insulating sheath having a distal end disposed about at least a portion thereof.
4. The RF system of claim 3 wherein the RF energy emitter is comprised of an uninsulated distal tip portion of the elongated RF energy transmitting member
15 which extends distally beyond the distal end of the insulating sheath.
5. The RF system of claim 4 wherein the uninsulated distal tip has a diameter of about 0.025 to about 0.20 inch configured to emit pulses of RF energy.
6. The RF system of claim 4 wherein the uninsulated distal tip has a length of about 0.1 to about 5 mm.

7. The RF system of claim 4 wherein the uninsulated distal tip has a length of about 1.5 to about 3.5 mm.

8. The RF system of claim 4 wherein the uninsulated distal tip has a diameter of about 0.04 to about 0.08 inch.

5 9. A system for ablating tissue in a wall of a patient's heart with one or more bursts of RF energy, comprising:

a) a source for RF energy;

b) a trigger signal generator operatively coupled to electrical signals generated by a patient's heart;

10 c) a control unit which is operatively coupled to the trigger signal generator and the source for RF energy, and which operates the source of RF energy upon receipt of trigger signals from the trigger signal generator so as to emit at least one burst of RF energy in response to a received trigger signal; and

15 d) an RF energy transmitting member having a proximal end which is configured to receive RF energy from the source, an elongated shaft configured to transmit RF energy received from said source and an uninsulated distal tip which is configured to emit transmitted RF energy to a patient's heart wall to ablate tissue therein.

20 10. The system of claim 9 wherein control unit controls the duration of the burst of RF energy.

11. The system of claim 9 wherein the trigger generator emits at least one trigger signal during a desired portion of the patient's heart cycle.

12. A method of forming a channel in a patient's heart wall, comprising:

5 a) providing an elongated RF energy transmitting device having proximal and distal ends and which includes an elongated insulated electrical conductor and an uninsulated distal tip configured to emit RF energy;

b) introducing the elongated RF energy transmitting device into the patient and advancing the elongated RF energy transmitting device therein until the uninsulated distal tip thereof is disposed adjacent to a surface of the patient's heart wall; and
10

c) emitting one or more bursts of RF energy from the uninsulated distal tip of the RF energy transmitting device over at least one interval from about 1 to about 500 msec to form a channel within the heart wall by ablating tissue therein.

15 13. The method of claim 12 wherein one or more bursts of RF energy are emitted from the distal tip over an interval of about 30 to about 130 msec.

14. The method of claim 12 wherein the channel is formed during a single interval.

15. The method of claim 12 wherein at least one burst of RF energy
20 emitted from the uninsulated distal tip comprises a plurality of pulses of RF energy.

16. The method of claim 15 wherein the individual pulses have durations of at least about one msec.

17. The method of claim 12 wherein from about 2 to about 10 bursts of RF energy are emitted from the uninsulated distal tip to form the channel.

5 18. A method of revascularizing a desired region of a patient's heart wall, comprising:

a) providing an elongated flexible RF energy transmitting device having proximal and distal ends and which includes an uninsulated distal tip configured to emit RF energy;

10 b) introducing the elongated flexible RF energy transmitting device into the patient's vasculature and advancing the elongated flexible RF energy transmitting device therein until the uninsulated distal tip thereof is disposed adjacent to and in contact with a surface of the patient's heart wall; and

15 c) delivering RF energy from a source thereof through the RF energy transmitting member to said uninsulated distal tip; and

d) emitting at least one burst of RF energy from the uninsulated distal tip of the elongated flexible RF energy transmitting device over an interval of about 1 to about 500 msec to ablate tissue in the desired region of
20 the patient's heart wall.

19. The method of claim 16 wherein the RF energy source has a peak power output of about 200 to about 500 watts.

20. A percutaneous method of revascularizing a desired region of a patient's heart wall, comprising:

5 a) providing an elongated flexible RF energy transmitting device having proximal and distal ends and which includes an elongated insulated electrical conducting member and an uninsulated distal tip configured to emit RF energy;

b) introducing the elongated flexible RF energy transmitting device into the patient's vasculature and advancing said device therein until the uninsulated distal tip thereof is disposed adjacent to and in contact with a surface of the patient's heart wall;

10

c) delivering at least one burst of RF energy over an interval of about 1 to about 500 msec from a source thereof through the RF energy transmitting device to the uninsulated distal tip thereof; and

d) emitting at least one transmitted burst of RF energy from the uninsulated distal tip to ablate tissue in the desired region of the patient's heart wall.

15

21. The method of claim 20 wherein a channel is formed by said tissue ablation.

22. The method of claim 20 wherein at least one burst of RF energy comprises a plurality of pulses of RF energy.

20

23. The method of claim 22 wherein each individual pulse of RF energy has a duration of at least one msec.

24. The method of claim 20 wherein the RF energy source has a peak power output of about 200 to about 500 watts.

25. A method of revascularizing a desired region of a patient's heart wall, comprising:

5 a) providing an RF energy transmitting member having proximal end, an elongated insulated shaft and an uninsulated distal tip configured to emit RF energy;

 b) introducing at least a distal portion of the RF energy transmitting member into the patient and advancing said member until the
10 uninsulated distal tip thereof is disposed adjacent to and in contact with a surface of the patient's heart wall; and

 c) during a desired period of the patient's heart cycle, emitting at least one burst of RF energy from the uninsulated distal tip of the elongated flexible RF energy transmitting member to ablate tissue in the desired region
15 of the patient's heart wall to revascularize the desired region.

26. The method of claim 25 wherein the RF energy emission is continuous during at least one of said bursts.

27. The method of claim 25 wherein the RF energy emission is discontinuous during at least one of said bursts.

20 28. The method of claim 27 wherein the discontinuous emission of RF energy is pulsatile during at least one of said bursts.

29. The method of claim 28 wherein the pulsatile RF energy emission is a train of pulses.

30. The method of claim 25 wherein at least one burst of RF energy is emitted from said uninsulated distal tip over an interval of about 1 to about 500
5 msec.

31. The method of claim 25 wherein at least one burst of RF energy is emitted from said uninsulated distal tip over an interval of about 30 to about 150 msec.

32. A method of forming a channel in a desired region of a patient's heart
10 wall, comprising:

- a) providing an RF energy transmitting member having a proximal end, an elongated insulated shaft and an uninsulated distal tip configured to emit RF energy;
- b) introducing at least a distal portion of the elongated RF energy
15 transmitting member into the patient until the uninsulated distal tip thereof is disposed adjacent to and in contact with a surface of the patient's heart wall;
and
- c) emitting at least one burst of RF energy from the uninsulated
20 distal tip over an interval of about 1 to about 500 msec to form a channel in the desired region of the patient's heart wall by ablating tissue therein.

33. The method of claim 32 including the step of detecting a desired period of the patient's heart cycle; and emitting said burst of RF energy from the uninsulated distal tip during the detected desired period.

34. The method of claim 33 wherein the desired period of the patient's heart cycle is between the R wave and the T wave of the patient's heart cycle.

35. A method of performing transmyocardial revascularization in a desired region of a wall of a patient's heart, comprising:

- a) providing an elongated device having proximal and distal ends and a thermal ablator located at the distal end;
- 10 b) introducing the device into the body of the patient and directing the distal end of the device to the desired region of the patient's heart wall wherein the transmyocardial revascularization procedure is to be performed; and
- 15 c) supplying energy to the thermal ablator to form a revascularization channel in the myocardium layer.

36. The method of claim 35 wherein the elongated device is a flexible intravascular device, further comprising the steps of:

- a) introducing the device into the patient's body by advancing the device through the patient's vasculature until a distal portion thereof is disposed within a chamber of the patient's heart defined by the wall;
- 20 b) directing the distal end of the device to the desired region of the patient's heart wall; and

c) supplying energy to the thermal ablator to first ablate tissue while performing the transmyocardial revascularization.

37. The method of claim 35 wherein the elongated device is configured to be introduced through the patient's chest wall, further comprising the steps of:

5 a) directing the distal end of the device to the epicardium layer of the desired region of the wall; and

b) supplying energy to the thermal ablator to remove tissue sequentially from the epicardium layer, the myocardium layer and the endocardium layer to form the revascularization channel.

10 38. The method of claim 36 wherein the thermal ablator is advanced through the endocardium layer at a first energy level and within the myocardium layer at a second energy level lower than the first energy level.

39. The method of claim 35 wherein the elongate device includes lumens for perfusing and aspirating the desired region of the heart wall, further comprising
15 the step of clearing the ablated tissue from the patient's heart.

40. The method of claim 35 further comprising the step of forming the revascularization channel with the thermal ablator at a temperature between about 60 to about 600° C.

41. The method of claim 35 wherein the thermal ablator comprises a
20 ferrite probe, further comprising the step of irradiating the probe with radiofrequency energy to form the revascularization channel.

42. The method of claim 41 wherein the revascularization channel are formed by irradiating the ferrite probe with radiofrequency energy at a frequency between about 30 MHz to about 10 GHz.

43. A method of forming a revascularization channel in a desired region of
5 a wall of a patient's heart, comprising:

- a) providing an elongated shaft having proximal and distal ends and an RF energy emitter located at the distal end;
- b) introducing the shaft into the body of the patient and directing the distal end of the device to the desired region of the wall wherein the
10 revascularization channel is to be formed; and
- c) supplying RF energy to the RF energy emitter to form a revascularization channel in the myocardial layer.

44. The method of claim 43 wherein the elongated shaft is a flexible intravascular shaft, further comprising the steps of:

- 15 a) introducing the shaft into the patient's body by advancing the shaft through the patient's vasculature until a distal portion thereof is disposed within a chamber of the patient's heart defined by the wall;
- b) directing the distal end of the shaft to the endocardial layer of the desired region of the wall; and
- 20 c) supplying RF energy to the RF energy emitter to first remove tissue from the endocardial layer when forming the revascularization channel.

45. The method of claim 43 wherein the elongated shaft is configured to be introduced through the patient's chest wall, further comprising the steps of:

a) directing the distal end of the shaft to the epicardial layer of the desired region of the wall; and

5 b) supplying RF energy to the RF energy emitter to remove tissue sequentially from the epicardial layer, the myocardial layer and the endocardial layer to form the revascularization channel.

46. The method of claim 44 wherein the RF energy emitter is advanced through the endocardial layer at a first energy level and within the myocardial layer
10 at a second energy level lower than the first energy level.

47. The method of claim 43 wherein the elongated shaft includes means for perfusing and aspirating the desired region of the heart wall, further comprising the step of clearing the removed tissue from the patient's heart.

48. The method of claim 43 wherein the RF energy emitter comprises a
15 probe connected to a first and second electrode which extend the length of the device, further comprising the step of supplying RF energy across the electrodes to form the revascularization channel.

49. The method of claim 48 wherein the revascularization channel is formed by supplying RF energy between about 30 MHz to about 10 GHz across the
20 electrodes.

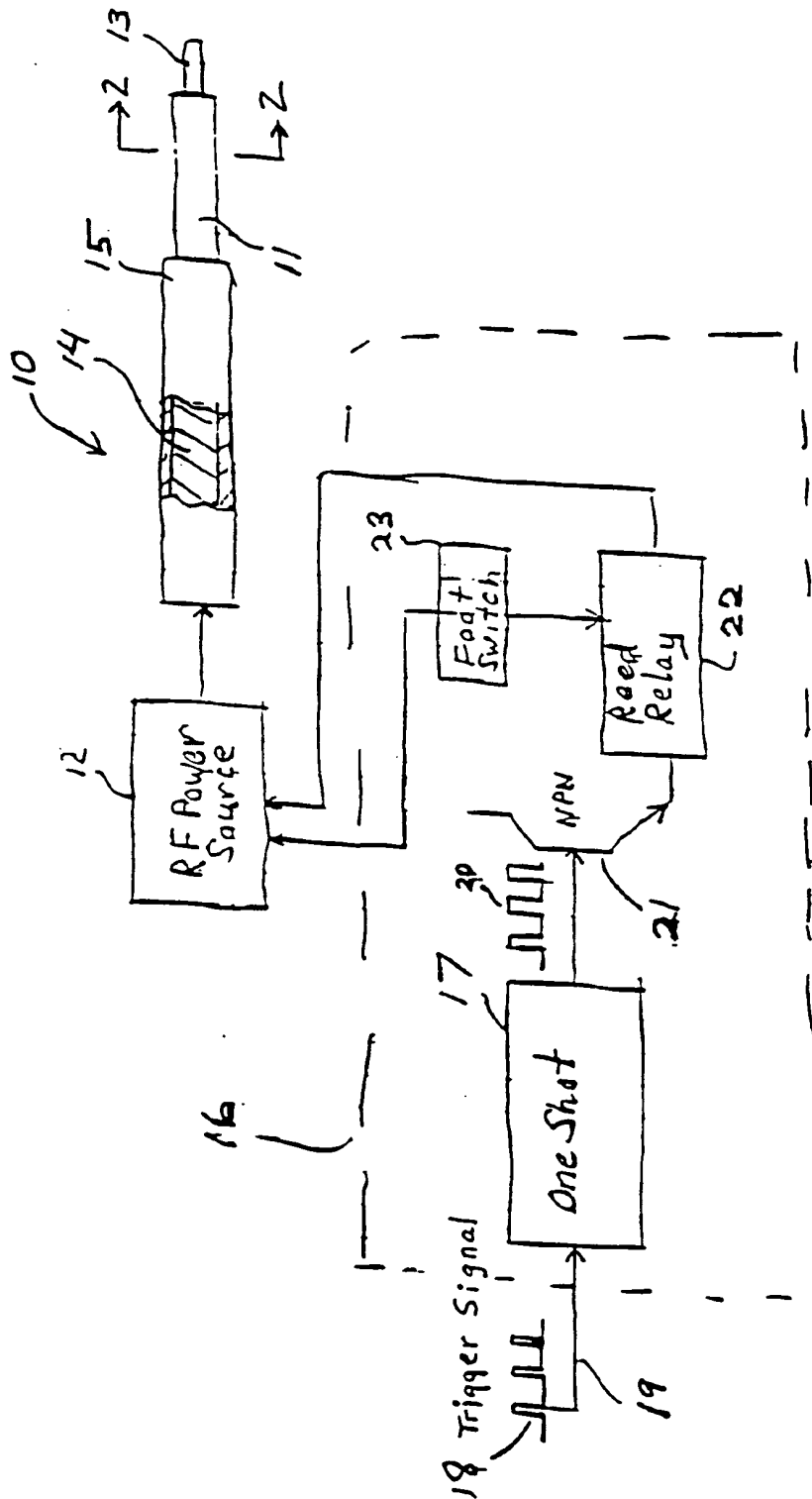


Fig. 1

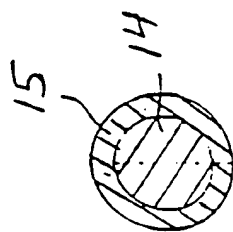


Fig. 2

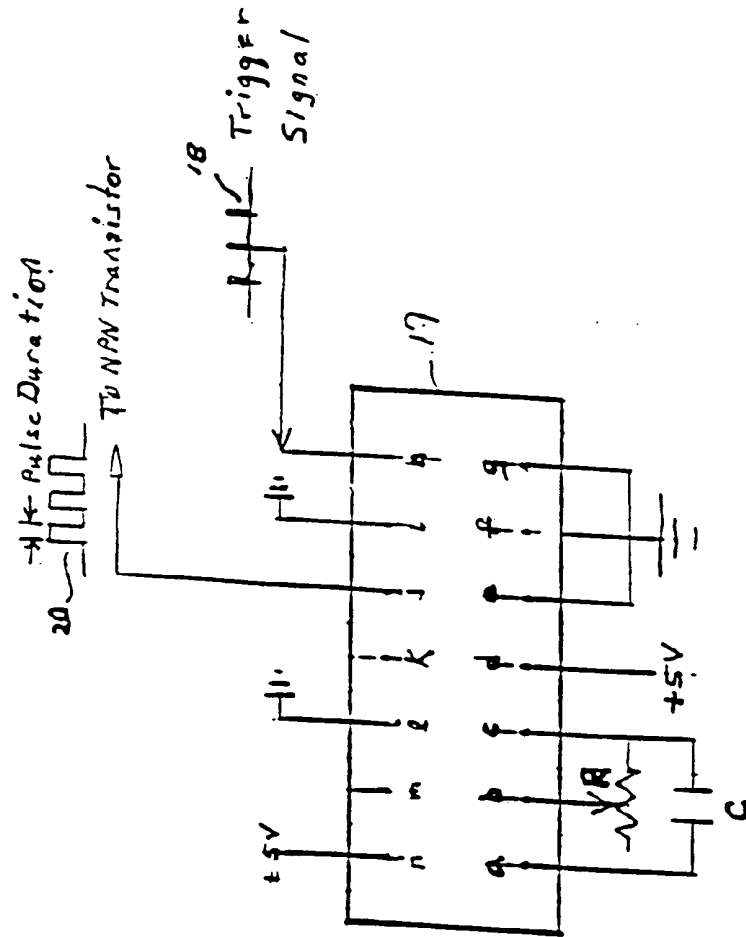


Fig. 3

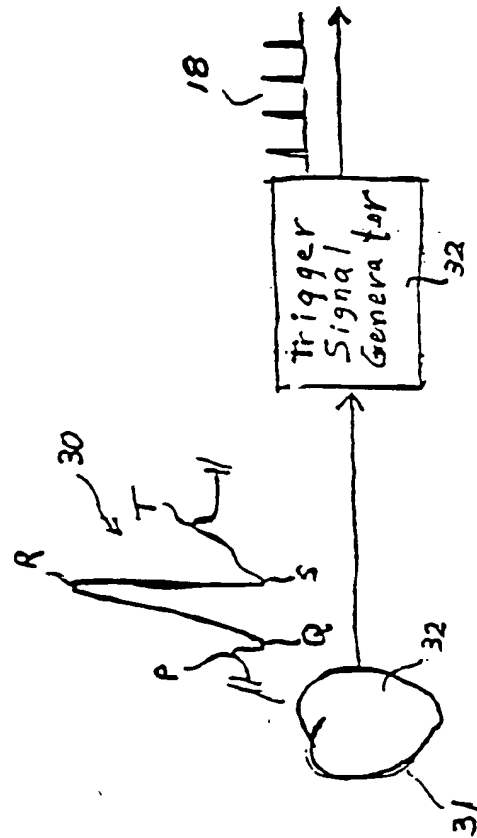


Fig. 4

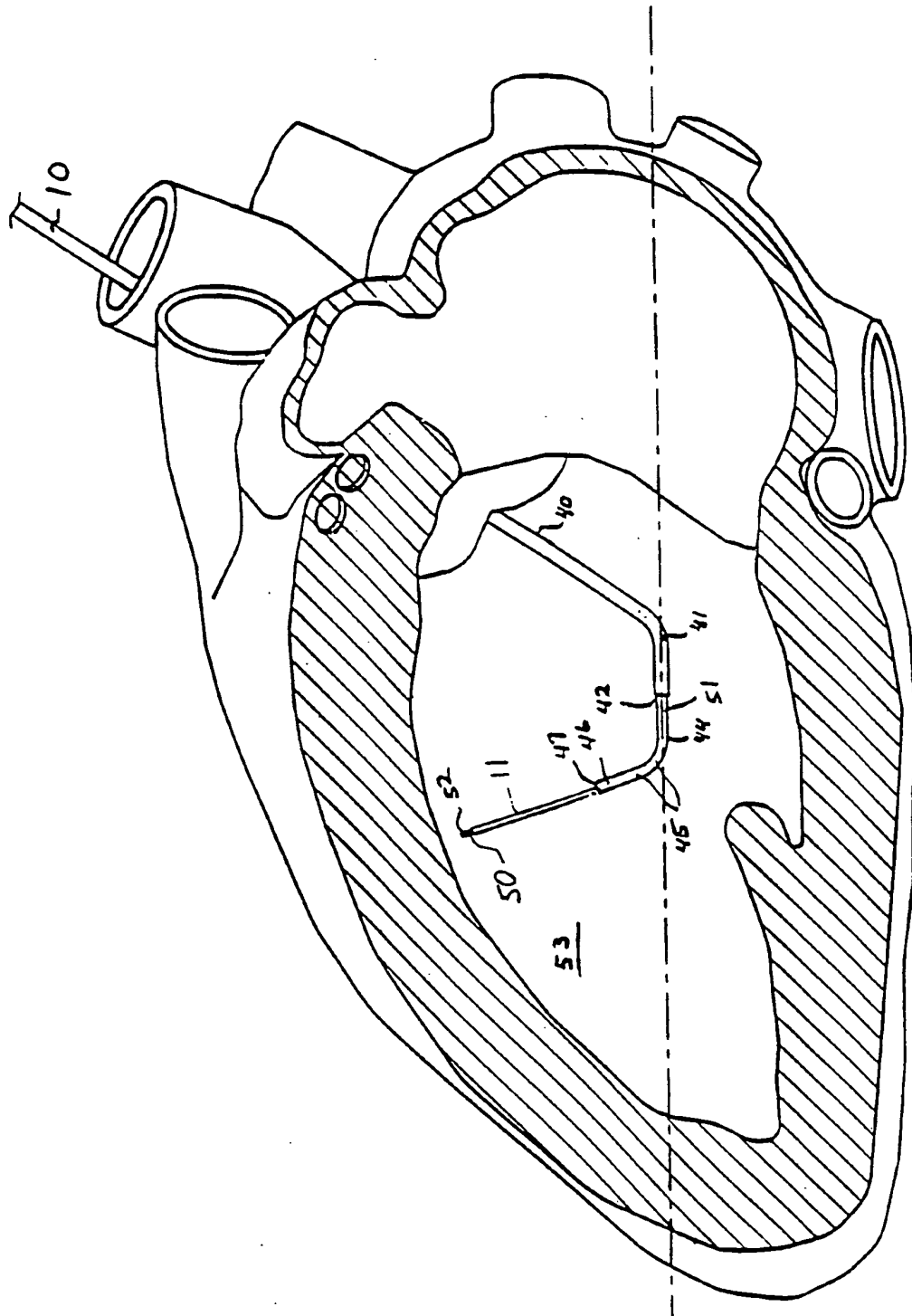


Fig. 5

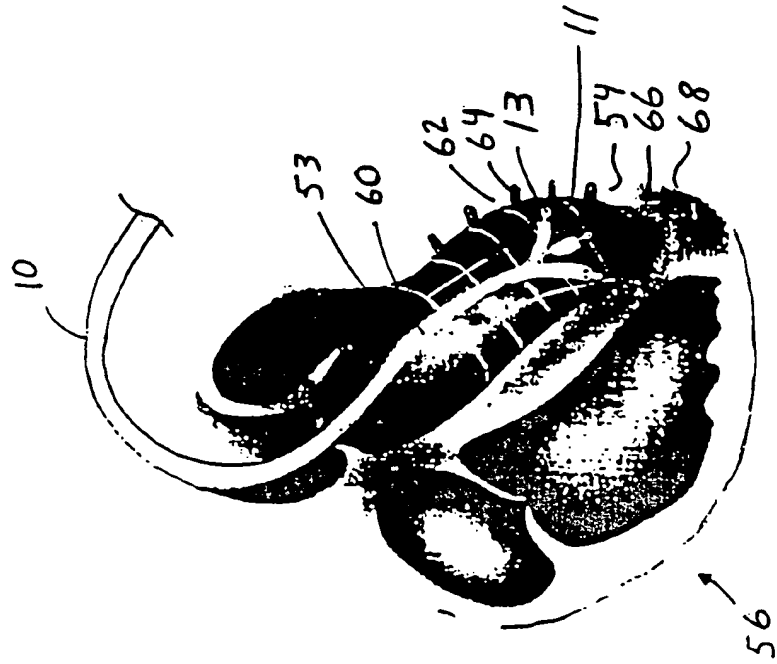


Fig. 6

BEST AVAILABLE COPY

PTMR

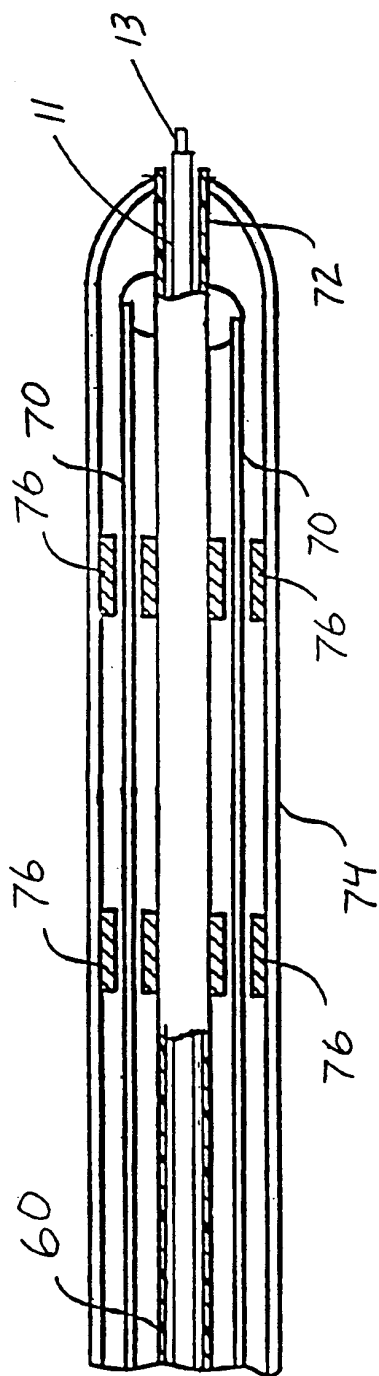


Fig. 7

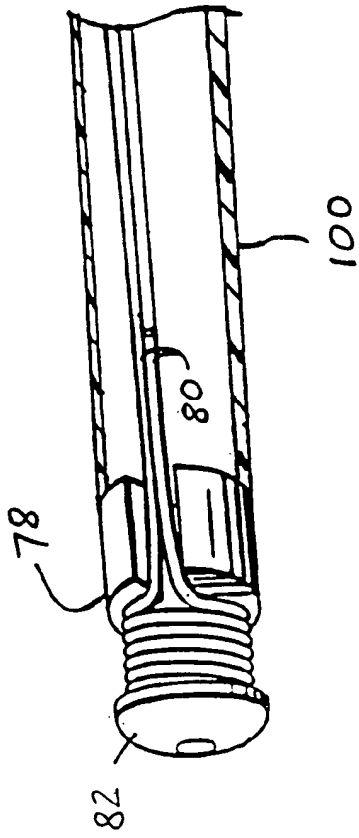


Fig. 8

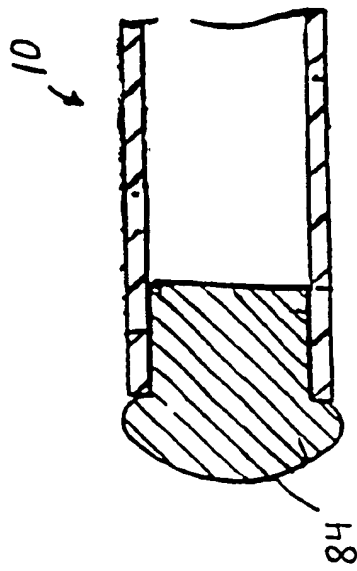


Fig. 9

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/US 98/20799

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 27897 A (TRANSVASCULAR) 7 August 1997	1, 2
Y	see page 13, line 10 - page 14, line 6 see page 37, line 10 - page 38, line 16; figures 29A-D	3-11
Y	WO 96 39967 A (EP TECHNOLOGIES) 19 December 1996 see page 30, line 9 - page 31, line 14; claims 1, 14, 46, 47, 53, 65	3-11
Y	EP 0 553 576 A (LASER ENGINEERING) 4 August 1993 see the whole document	11
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

13 January 1999

Date of mailing of the international search report

20/01/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2250 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Raybould, B

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/20799

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 35469 A (CARDIOGENESIS) 14 November 1996	1,2
A	see page 1, line 14 - page 2, line 28 see page 8, line 27 - page 9, line 4 see claims 26,31	9
A	US 5 672 170 A (CHO ET AL) 30 September 1997 see the whole document	11
X,P	EP 0 858 779 A (ECLIPSE SURGICAL TECHNOLOGIES) 19 August 1998	1,2
A	see page 7, column 1, line 4 - line 6 see page 11, column 1, line 21 - line 48	9

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 98/20799

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/20799

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9727897	A	07-08-1997	AU 1847197 A	22-08-1997
			AU 1847297 A	22-08-1997
			AU 1847397 A	22-08-1997
			AU 7431696 A	30-04-1997
			CA 2234361 A	17-04-1997
			CA 2244066 A	07-08-1997
			CA 2244079 A	07-08-1997
			CA 2244080 A	07-08-1997
			EP 0879068 A	25-11-1998
			WO 9713463 A	17-04-1997
			WO 9727893 A	07-08-1997
			WO 9727898 A	07-08-1997
WO 9639967	A	19-12-1996	NONE	
EP 553576	A	04-08-1993	CA 2060145 A,C	29-07-1993
			US 5125926 A	30-06-1992
			DE 69210007 D	23-05-1996
			DE 69210007 T	19-12-1993
WO 9635469	A	14-11-1996	CA 2220689 A	14-11-1996
US 5672170	A	30-09-1997	NONE	
EP 858779	A	19-08-1998	AU 5279898 A	26-03-1998
			CA 2228935 A	03-08-1998
			JP 10229988 A	02-09-1998

THIS PAGE BLANK (USPTO)